

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

RAYMOND SIEGER, individually and  
as Administrator of THE ESTATE OF  
SUSAN G. SIEGER

Plaintiffs,

vs.

OCTAPHARMA USA, INC.

Defendant.

**CIVIL ACTION NO.**

**COMPLAINT**

NOW COMES the Plaintiff, Raymond Sieger, individually and as Administrator of The Estate of Susan G. Sieger, by and through his undersigned counsel, to file this Complaint and in support thereof asserts as follows:

**PARTIES**

1. Plaintiff, Raymond Sieger, is a citizen of the Commonwealth of Pennsylvania residing at 9 Goodrock Road, Levittown, PA 19057, Bucks County, Pennsylvania.
2. Plaintiff was the husband of Susan G. Sieger, deceased, who was born on October 23, 1956 and died on or about November 13, 2011. Susan G. Sieger was a resident of the Commonwealth of Pennsylvania and resided in Bucks County, Pennsylvania at the time of her death.
3. Plaintiff was appointed as Administrator of the Estate of Susan G. Sieger on or about November 22, 2011 by the Register of Wills of Bucks County, Pennsylvania, at File No. 09-11-2875.

4. Defendant, Octapharma USA, Inc., is a Virginia Corporation authorized to conduct business in the Commonwealth of Pennsylvania and having a place of business at 121 River Street, Hoboken, NJ 07030.

#### **JURISDICTION AND VENUE**

5. Defendant, Octapharma USA, Inc., is in the business, among other things, of designing, manufacturing, producing, selling, distributing, marketing and/or otherwise placing into the stream of commerce medicines derived from human proteins, to include Octagam (Immune Globuline Intravenous (human)) 5% Liquid Preparation ("Octagam"), and carries on regular and substantial business throughout the Commonwealth of Pennsylvania.

6. At all relevant times, Octapharma USA, Inc. acted through its duly authorized agents, servants and employees, who were acting in the course and scope of their employment and in furtherance of the business of Octapharma USA, Inc.

7. The Court has subject matter jurisdiction over this case under 28 U.S.C. § 1332(a) based upon diversity of citizenship between the parties and the fact that the amount in controversy, exclusive of costs and interest, exceeds the sum of \$75,000.00.

8. Venue in the Eastern District of Pennsylvania is proper under 28 U.S.C. § 1391 because:

- a. Defendant regularly conducts business in Pennsylvania, to include this district and enters its products into the stream of commerce in this district;
- b. Defendant marketed and advertised in this district, and/or their marketing and advertising material was distributed, disseminated, or entered the borders of this district;
- c. Upon information and belief, Defendant has received substantial revenue and profits from sales of its products in this district.
- d. Susan G. Sieger was a citizen and resident of Bucks County, Pennsylvania at all times relevant to this Complaint, including at the times she received infusions of Defendant's product.

9. Pursuant to a series of tolling agreements entered into between Plaintiff and Defendant, the statute of limitations in this matter has been tolled until November 29, 2013.

#### **FACTUAL BACKGROUND**

10. Susan G. Sieger was diagnosed with multiple sclerosis in the early 1990s.

11. The treatment of Mrs. Sieger's multiple sclerosis included periodic infusions of Octagam.

12. The infusions of Octagam administered to Mrs. Sieger included, but were not limited to, infusions performed on July 1, 2010 and July 2, 2010.

13. On or about July 5, 2010, at approximately 10:00 p.m., Mrs. Sieger was observed to have slurred speech. At approximately 12:30 a.m. on July 6, 2010, she was found on the floor of her home and was unable to move her right upper and lower extremities.

14. Mrs. Sieger thereafter presented to the Aria Health Frankford Hospital for emergency treatment, was admitted at approximately 1:23 a.m., and was diagnosed as having suffered an acute stroke.

15. On or about July 6, 2010, Mrs. Sieger was transported by helicopter to Thomas Jefferson University Hospital in Philadelphia where she was ultimately admitted to the stroke unit. Mrs. Sieger was discharged to an acute rehabilitative facility on or about July 14, 2010 with a primary discharge diagnosis of stroke.

16. Following her stroke on July 5, 2010, Mrs. Sieger was physically incapable of caring for herself and after receiving rehabilitative therapy, was confined to a skilled nursing facility.

17. On or about August 20, 2010, Defendant initiated a voluntary market withdrawal of selected lots of Octagam as a result of an increased number of stroke events experienced by patients who received Octagam.

18. The Octagam administered to Susan G. Sieger included Octagam from the lots selected for voluntary withdrawal.

19. On or about September 24, 2010, Defendant initiated a voluntary market withdrawal of all Octagam in the United States market.

20. Upon information and belief, Defendant conducted an investigation to determine the biomechanical root cause of the increased number of stroke events associated with its Octagam product. According to public statements made by Defendant, the biomechanical root cause was determined to be procoagulant impurities introduced as part of the manufacturing process or otherwise associated with the manufacturing process, to include the presence of activated Factor XI.

21. The stroke suffered by Susan G. Sieger was a direct and proximate result of the administration of defective Octagam administered to her prior to the stroke.

22. As a direct and proximate result of the administration of defective Octagam and her resulting stroke, Mrs. Sieger's condition rapidly deteriorated and she underwent multiple hospital admissions for various physical ailments including, but not limited to, sepsis, recurrent urinary tract infections, bullous pemphigoid, acute renal failure, decubitus ulcers, pneumonia, c-difficile infection, deep vein thrombosis, osteomyelitis, hypovolemia and septic shock.

23. As a direct and proximate result of the administration of defective Octagam, the resulting stroke and her resulting deteriorated condition, Mrs. Sieger died on or about November 13, 2011.

24. As a direct and proximate result of the administration of defective Octagam, the resulting stroke and her resulting deteriorated condition, Mrs. Sieger suffered physical pain and suffering and mental anguish.

25. As a direct and proximate result of the administration of defective Octagam, the resulting stroke and her resulting deteriorated condition, Mrs. Sieger suffered injuries that precluded her from enjoying the ordinary pleasures of life and from participating in and enjoying her usual duties, activities and avocations.

26. As a direct and proximate result of the administration of defective Octagam, the resulting stroke and her resulting deteriorated condition, Mrs. Sieger was forced to undergo rehabilitative and other treatments, procedures, care and therapy.

27. As a direct and proximate result of the administration of defective Octagam, the resulting stroke and her resulting deteriorated condition, Mrs. Sieger incurred expenses for medical care and treatment.

28. As a direct and proximate result of the infusion of defective Octagam, the resulting stroke and her resulting deteriorated condition, Mrs. Sieger was at increased risk of harm including, but not limited to, death and other physical ailments.

**COUNT I – STRICT LIABILITY**

29. Plaintiff hereby incorporates by reference the allegations contained in the foregoing paragraphs as though the same were more fully set forth at length herein.

30. Defendant's Octagam product was defective and unreasonably dangerous for its intended use in its design and/or manufacture, including, but not limited to, the following particular defects:

- a. The Octagam product contained hazardous levels of procoagulant impurities including, but not limited to, activated Factor XI, that placed persons who were administered the Octagam product at increased risk of suffering a stroke;
- b. The Octagam product was designed and/or manufactured without implementing corrective and preventative measures for in-process identification of hazardous levels of procoagulant impurities including, but not limited to, activated Factor XI;
- c. The Octagam product was designed and/or manufactured without implementing corrective and preventative measures for final product testing and identification of hazardous levels of procoagulant impurities including, but not limited to, activated Factor XI;
- d. The Octagam product was designed and/or manufactured without implementing a thrombin generation assay or a similar test to assess an increased procoagulant potential;
- e. The Octagam product was designed and/or manufactured without implementing an adsorption step for removal of procoagulant impurities including, but not limited to, activated Factor XI;
- f. The Octagam product was designed and/or manufactured without implementing quality control testing to detect the presence of hazardous levels of procoagulant impurities including, but not limited to, activated Factor XI;
- g. The Octagam product was designed and/or manufactured without adequate and proper warnings regarding its hazardous nature;
- h. The Octagam product was designed and/or manufactured without adequate and proper tests and inspections;
- i. The Octagam product was designed and/or manufactured in violation of applicable statutes and regulations, safety codes and recognized industry standards;
- j. The Octagam product was designed and/or manufactured in such manner that it had a hazardous propensity and/or an increased hazardous propensity to cause stroke.
- k. The Octagam product was designed and/or manufactured without including every element or step necessary to make it safe for its intended use; and
- l. The Octagam product was designed and/or manufactured so as to place persons who were administered the Octagam product at increased risk of suffering a stroke.

31. The Octagam product was at all relevant times in Defendant's possession or control.

32. Defendant was under a duty to warn and to recall the defective product and Defendant breached these duties by failing to timely warn or to timely recall the defective product.

33. The defective and unreasonably dangerous design and/or manufacture of the Octagam product was a direct and proximate cause of Susan G. Sieger's stroke and subsequent death and Defendant is strictly liable for the resulting injuries and losses.

34. Defendant's failure to timely warn and to recall the Octagam product was a direct and proximate cause of Susan G. Sieger's stroke and subsequent death and Defendant is strictly liable for the resulting injuries and losses.

35. Defendant's conduct as set forth above was outrageous, malicious, wanton, willful and oppressive and demonstrates a reckless indifference to the interests of others such that an award of punitive damages is necessary.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages in an amount in excess of \$75,000.00, together with interest, attorney's fees and costs of suit.

#### **COUNT II – BREACH OF WARRANTY**

36. Plaintiff hereby incorporates by reference the allegations contained in the foregoing paragraphs as though the same were more fully set forth at length herein.

37. Defendant impliedly and expressly warranted that the Octagam product was safe for the purposes for which it was intended, including the uses made of the product by Plaintiff.

38. Defendant breached its implied and express warranties in that, for the reasons set forth above, the Octagam product was defective, hazardous, dangerous, unfit for use, not properly merchantable and not safe for its intended ordinary and foreseeable use and purpose.

39. Defendant's breach of said warranties was a direct and proximate cause of Susan G. Sieger's stroke and subsequent death and Defendant is liable for the resulting injuries and losses.

40. Defendant's conduct as set forth above was outrageous, malicious, wanton, willful and oppressive and demonstrates a reckless indifference to the interests of others such that an award of punitive damages is necessary.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages in an amount in excess of \$75,000.00, together with interest, attorney's fees and costs of suit.

### **COUNT III - NEGLIGENCE**

41. Plaintiff hereby incorporates by reference the allegations contained in the foregoing paragraphs as though the same were more fully set forth at length herein.

42. At all times, Defendant knew or should have known that the Octagam product was dangerous, defective and presented a risk of severe injury or death to persons who were administered the Octagam product, such as Susan G. Sieger.

43. Defendant was under a duty to take reasonable steps to prevent foreseeable harm to persons who were administered the Octagam product, such as Susan G. Sieger.

44. Susan G. Sieger's stroke and subsequent death and the resulting injuries and losses, as set forth above, were directly and proximately caused by Defendant's negligence generally and in the following particulars:



- a. Designing, manufacturing, selling, distributing and/or otherwise placing the Octagam product into the stream of commerce when it contained hazardous levels of procoagulant impurities including, but not limited to, activated Factor XI, that placed persons who were administered the Octagam product at increased risk of suffering a stroke;
- b. Designing, manufacturing, selling, distributing and/or otherwise placing the Octagam product into the stream of commerce without implementing corrective and preventative measures for in-process identification of hazardous levels of procoagulant impurities including, but not limited to, activated Factor XI;
- c. Designing, manufacturing, selling, distributing and/or otherwise placing the Octagam product into the stream of commerce without implementing corrective and preventative measures for final product testing and identification of hazardous levels of procoagulant impurities including, but not limited to, activated Factor XI;
- d. Designing, manufacturing, selling, distributing and/or otherwise placing the Octagam product into the stream of commerce without implementing a thrombin generation assay or a similar test to assess an increased procoagulant potential;
- e. Designing, manufacturing, selling, distributing and/or otherwise placing the Octagam product into the stream of commerce without implementing an adsorption step for removal of procoagulant impurities including, but not limited to, activated Factor XI;
- f. Designing, manufacturing, selling, distributing and/or otherwise placing the Octagam product into the stream of commerce without implementing quality control testing to detect the presence of hazardous levels of procoagulant impurities including, but not limited to, activated Factor XI;
- g. Designing, manufacturing, selling, distributing and/or otherwise placing the Octagam product into the stream of commerce without adequate and proper warnings regarding its hazardous nature;
- h. Designing, manufacturing, selling, distributing and/or otherwise placing the Octagam product into the stream of commerce without adequate and proper tests and inspections;
- i. Designing, manufacturing, selling, distributing and/or otherwise placing the Octagam product into the stream of commerce in violation of applicable statutes and regulations, safety codes and recognized industry standards;
- j. Designing, manufacturing, selling, distributing and/or otherwise placing the Octagam product into the stream of commerce when it had a hazardous propensity and/or an increased hazardous propensity to cause stroke.

- k. Designing, manufacturing, selling, distributing and/or otherwise placing the Octagam product into the stream of commerce without including every element or step necessary to make it safe for its intended use; and
- l. Designing, manufacturing, selling, distributing and/or otherwise placing the Octagam product into the stream of commerce so as to place persons who were administered the Octagam product at increased risk of suffering a stroke.

45. Defendant's conduct as set forth above was outrageous, malicious, wanton, willful and oppressive and demonstrates a reckless indifference to the interests of others such that an award of punitive damages is necessary.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages in an amount in excess of \$75,000.00, together with interest, attorney's fees and costs of suit.

#### **COUNT IV – WRONGFUL DEATH**

46. Plaintiff incorporates the allegations contained in the foregoing paragraphs as though fully set forth at length herein.

47. Susan G. Sieger's death was factually caused by the conduct of Defendant as set forth herein.

48. Plaintiff is the Administrator of the Estate of Susan G. Sieger and brings this action to recover all benefits under applicable sections of the Wrongful Death Act, 42 Pa.C.S. § 8301, on behalf of all those persons entitled to recover under the law.

49. Plaintiff claims on behalf of the Estate of Susan G. Sieger, and on behalf of himself and all those persons entitled to recover under the law, including but not limited to:

- (a) All amounts necessary to cover all hospital, medical, funeral, burial, and estate administration expenses incurred;
- (b) An amount that will fairly and adequately compensate the family of the decedent for their loss of any contributions they would have received

between the time of the death of the decedent and the end of her life expectancy, including all amounts of money that the decedent would have spent for or given to her family for such items as shelter, food, clothing, medical care, education, entertainment, gifts, and recreation;

- (c) An amount that will fairly and adequately compensate her family for the monetary value of the services, society, and comfort that she would have given to her family had she lived, including such elements as work around the home, provision of physical comforts and services, and provision of society and comfort; and
- (d) An amount that will fairly compensate for the loss of the services that the decedent as a mother would have contributed to her children, including the value of such services as guidance, tutelage, and moral upbringing that you believe the children would have received, up to the time such services would have been provided, had the death not occurred.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages in an amount in excess of \$75,000.00, together with interest, attorney's fees and costs of suit.

#### **COUNT V - SURVIVAL**

50. Plaintiff incorporates the allegations contained in the foregoing paragraphs as though fully set forth at length herein.

51. Plaintiff brings this action on behalf of the Estate of Susan G. Sieger, deceased, to recover all benefits and damages under the Survival Act, 42 Pa.C.S. § 8302, on behalf of himself and all other persons entitled to recover under the law.

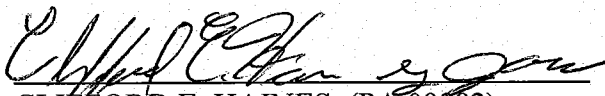
52. Plaintiff claims on behalf of the Estate of Susan G. Sieger, deceased, all damages suffered by the Estate of Susan G. Sieger and on behalf of all other persons entitled to recover under the law, all damages permitted, including but not limited to:

- (a) The total amount the decedent would have earned between the time of her stroke and her death;

- (b) The total net earnings decedent would have earned between the date of her death and the end of her life expectancy; and
- (c) An amount to fairly and adequately compensate for the mental and physical pain, suffering, and inconvenience and loss of life's pleasures that the decedent endured from the moment of her injury to the moment of her death.

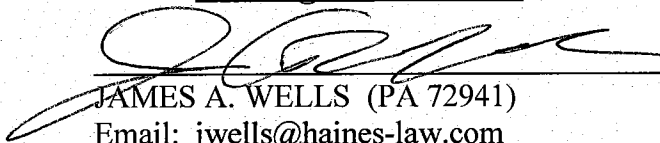
WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages in an amount in excess of \$75,000.00, together with interest, attorney's fees and costs of suit.

Respectfully submitted,



CLIFFORD E. HAINES (PA 09882)

Email: [chains@haines-law.com](mailto:chains@haines-law.com)



JAMES A. WELLS (PA 72941)

Email: [jwells@haines-law.com](mailto:jwells@haines-law.com)

Haines & Associates  
1835 Market Street  
Suite 2420  
Philadelphia, PA 19103  
Telephone: 215-246-2200  
Fax: 215-246-2211  
Attorneys for Plaintiff

#### DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues.



Clifford E. Haines

James A. Wells

Attorneys for Plaintiff

Dated: 11/27/13